(5)

No. 98-1152

IN THE

Supreme Court of the United States

OCTOBER TERM, 1998

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

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APPENDIX TO RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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APPENDIX

PUBLIC LAWS AND STATUTORY PROVISIONS

Public Law 89-92
89th Congress

AN ACT

To regulate the labeling of cigarettes,
and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Cigarette Labeling and Advertising Act".

DECLARATION OF POLICY

SEC. 2. It is the policy of the Congress, and the purpose of this Act, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

(1) the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes; and

(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

DEFINITIONS

SEC. 3. As used in this Act—

(1) The term "cigarette" means—

(A) any roll of tobacco wrapped in paper or any substance not containing tobacco, and

(B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

(2) The term "commerce" means (A) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, [illegible]erican Samoa, Wake Island, Midway Islands, [illegible]gman Reef, or Johnston Island.

(3) The term "United States", when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puertc Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island.

(4) The term "package" means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

(5) The term "person" means an individual, partnership, corporation, or any other business or legal entity.

(6) The term "sale or distribution" includes sampling or any other distribution not for sale.

LABELING

SEC. 4. It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes the package of which fails to bear the following statement: "Caution: Cigarette Smoking May Be Hazardous to Your Health." Such statement shall be located in a conspicuous place on every cigarette package and shall appear in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the package.

PREEMPTION

SEC. 5. (a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.

(b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

(c) Except as is otherwise provided in subsections (a) and (b), nothing in this Act shall be construed to limit, restrict, expand, or otherwise affect, the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes, nor to affirm or deny the Federal Trade Commission's holding that it has the authority to issue trade regulation rules or to require an affirmative statement in any cigarette advertisement.

(d)(1) The Secretary of Health, Education, and Welfare shall transmit a report to the Congress not later than

eighteen months after the effective date of this Act, and annually thereafter, concerning (A) current information on the health consequences of smoking and (B) such recommendations for legislation as he may deem appropriate.

(2) The Federal Trade Commission shall transmit a report to the Congress not later than eighteen months after the effective date of this Act, and annually thereafter, concerning (A) the effectiveness of cigarette labeling, (B) current practices and methods of cigarette advertising and promotion, and (C) such recommendations for legislation as it may deem appropriate.

CRIMINAL PENALTY

SEC. 6. Any person who violates the provisions of this Act shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than $10,000.

INJUNCTION PROCEEDINGS

SEC. 7. The several district courts of the United States are invested with jurisdiction, for cause shown, to prevent and restrain violations of this Act upon the application of the Attorney General of the United States acting through the several United States attorneys in their several districts.

CIGARETTES FOR EXPORT

SEC. 8. Packages of cigarettes manufactured, imported, or packaged (1) for export from the United States or (2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the United States shall be exempt from the requirements of this Act, but such exemptions shall not apply to cigarettes manufactured, imported, or packaged for sale or distribution to members or units of the Armed

Forces of the United States located outside of the United States.

SEPARABILITY

SEC. 9. If any provision of this Act or the application thereof to any person or circumstances is held invalid, the other provisions of this Act and the application of such provision to other persons or circumstances shall not be affected thereby.

TERMINATION OF PROVISIONS AFFECTING REGULATION OF ADVERTISING

SEC. 10. The provisions of this Act which affect the regulation of advertising shall terminate on July 1, 1969, but such termination shall not be construed as limiting, expanding, or otherwise affecting the jurisdiction or authority which the Federal Trade Commission or any other Federal agency had prior to the date of enactment of this Act.

EFFECTIVE DATE

SEC. 11. This Act shall take effect on January 1, 1966.

Approved July 27, 1965.

Public Law 91-222
91st Congress

AN ACT

To extend public health protection with respect to cigarette smoking and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Public Health Cigarette Smoking Act of 1969".

SEC. 2. Sections 2 through 10 of Public Law 89-92 (15 U.S.C. 1331-1338) are amended to read as follows:

"DECLARATION OF POLICY

"SEC. 2. It is the policy of the Congress, and the purpose of this Act, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

"(1) the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes; and

"(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

"DEFINITIONS

"SEC. 3. As used in this Act—

"(1) The term 'cigarette' means—

"(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and

"(B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

"(2) The term 'commerce' means (A) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island.

"(3) The term 'United States', when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term 'State' includes any political division of any State.

"(4) The term 'package' means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

"(5) The term 'person' means an individual, partnership, corporation, or any other business or legal entity.

"(6) The term 'sale or distribution' includes sampling or any other distribution not for sale.

"LABELING

"SEC. 4. It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes the package of which fails to bear the following statement: 'Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health'. Such statement shall be located in a conspicuous place on every cigarette package and shall appear in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the package.

"PREEMPTION

"SEC. 5. (a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.

"(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

"UNLAWFUL ADVERTISEMENTS

"SEC. 6. After January 1, 1971, it shall be unlawful to advertise cigarettes on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission.

"FEDERAL TRADE COMMISSION

"SEC. 7. (a) The Federal Trade Commission shall not take any action before July 1, 1971, with respect to its

pending trade regulation rule proceeding relating to cigarette advertising. If at any time on or after July 1, 1971, the Federal Trade Commission determines it is necessary to take action with respect to such pending trade regulation rule proceeding, it shall notify the Congress of the determination. Such notification shall include the text of the trade regulation rule and a full statement of the basis for such determination. No trade regulation rule adopted in such proceeding may take effect until six months after the Commission has notified the Congress of the text of such rule, in order that the Congress may act if it so desires.

"(b) Except as provided in subsection (a), nothing in this Act shall be construed to limit, restrict, expand, or otherwise affect the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes.

"(c) Nothing in this Act shall be construed to affirm or deny the Federal Trade Commission's holding that it has the authority to issue trade regulation rules or to require an affirmative statement in any cigarette advertisement.

"REPORTS

"SEC. 8. (a) The Secretary of Health, Education, and Welfare shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter, concerning (A) current information in the health consequences of smoking, and (B) such recommendations for legislation as he may deem appropriate.

"(b) The Federal Trade Commission shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter, concerning (A) the effectiveness of cigarette labeling, (B) current practices and methods

of cigarette advertising and promotion, and (C) such recommendations for legislation as it may deem appropriate.

"CRIMINAL PENALTY

"SEC. 9. Any person who violates the provisions of this Act shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than $10,000.

"INJUNCTION PROCEEDINGS

"SEC. 10. The several district courts of the United States are invested with jurisdiction, for cause shown, to prevent and restrain violations of this Act upon the application of the Attorney General of the United States acting through the several United States attorneys in their several districts.

"CIGARETTES FOR EXPORT

"SEC. 11. Packages of cigarettes manufactured, imported, or packaged (1) for export from the United States or (2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the United States shall be exempt from the requirements of this Act, but such exemptions shall not apply to cigarettes manufactured, imported, or packaged for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

"SEPARABILITY

"SEC. 12. If any provision of this Act or the application thereof to any person or circumstances is held invalid, the other provisions of this Act and the application of such provision to other persons or circumstances shall not be affected thereby."

SEC. 3. Section 5 of the amendment made by this Act shall take effect as of July 1, 1969. Section 4 of the amendment made by this Act shall take effect on the first day of the seventh calendar month which begins after the date of the enactment of this Act. All other provisions of the amendment made by this Act except where otherwise specified shall take effect on January 1, 1970.

Approved April 1, 1970.

Public Law 98-24
98th Congress

ALCOHOL AND DRUG ABUSE AMENDMENTS OF 1983

An Act to remedy alcohol and drug abuse.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE; STATEMENT OF POLICY

SECTION 1. (a) This Act may be cited as the "Alcohol and Drug Abuse Amendments of 1983".

(b) It is the policy of the United States and the purpose of this Act to provide leadership in the national effort to reduce the incidence of alcoholism and alcohol-related problems and drug abuse through—

(1) a continued Federal commitment to research into the behavioral and biomedical etiology, the treatment, and the mental and physical health and social and economic consequences of alcohol abuse and alcoholism and drug abuse;

(2) a commitment to—

(A) extensive dissemination to States, units of local government, community organizations, and private groups of the most recent information and research findings with respect to alcohol abuse and alcoholism and drug abuse, including information with respect to the application of research findings; and

(B) the accomplishment of such dissemination through up-to-date publications, demonstrations, educational programs, and other appropriate means;

(3) the provision of technical assistance to research personnel; services personnel, and prevention personnel in the field of alcohol abuse and alcoholism and drug abuse;

(4) the development and encouragement of prevention programs designed to combat the spread of alcoholism, alcohol abuse, drug abuse, and the abuse of other legal and illegal substances;

(5) the development and encouragement of effective occupational prevention and treatment programs within Government and in cooperation with the private sector; and

(6) the provision of a Federal response to alcohol abuse and alcoholism and drug abuse which encourages the greatest participation by the private sector, both financially and otherwise, and concentrates on carrying out functions relating to alcohol abuse and alcoholism and drug abuse which are truly national in scope.

THE ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION AND THE NATIONAL INSTITUTE OF MENTAL HEALTH, THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM, AND THE NATIONAL INSTITUTE ON DRUG ABUSE

SEC. 2. (a)(1) Title V of the Public Health Service Act is transferred to the end of the Public Health Service Act and redesignated as title XXI and sections 501 through 515 are redesignated as sections 2101 through 2115, respectively.

(2) Sections 217(c), 217(d), and 384 of the Public Health Service Act (42 U.S.C. 218 and 278) are each

amended by striking out "501" and inserting in lieu thereof "2101".

(b)(1) The Public Health Service Act is amended by inserting after title IV a new title designated as follows:

"TITLE V—ADMINISTRATION AND COORDINATION OF THE NATIONAL INSTITUTE OF MENTAL HEALTH, THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM, AND THE NATIONAL INSTITUTE ON DRUG ABUSE

"PART A—ADMINISTRATION AND INSTITUTES".

(2) Section 210 of the Act of May 14, 1974 (42 U.S.C. 3511) is transferred to title V of the Public Health Service Act established by paragraph (1), redesignated as section 501, and amended—

(A) by striking out "of Health, Education, and Welfare" each place it occurs;

(B) in subsection (c), by striking out "of the Public Health Service Act";

(C) by amending subsection (d) to read as follows:

"(d) To educate the public with respect to the health hazards of alcoholism, alcohol abuse, and drug abuse, the Administrator shall take such actions as may be necessary to ensure the widespread dissemination of current publications of the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse relating to the most recent research findings with respect to such health hazards.";

(D) by adding at the end the following:

"(e)(1) There shall be in the administration an Associate Administrator for Prevention to whom the Administrator shall delegate the function of promoting the prevention research programs of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse and coordinating such programs between the institutes and between the institutes and other public and private entities.

"(2) On or before January 1, 1984, and annually thereafter, the Administrator, acting through the Associate Administrator for Prevention, shall submit to the Congress a report describing the prevention activities (including preventive medicine and health promotion) undertaken by the administration, the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. The report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

"(f) The Administrator shall establish a process for the prompt and appropriate response to information provided the Administrator respecting (1) scientific fraud in connection with projects for which funds have been made available under this Act, and (2) incidences of violations of the rights of human subjects of research for which funds have been made available under this title. The process shall include procedures for the receiving of reports of such information from recipients of funds under this title and taking appropraite action with respect to such fraud and violations.".

(3) Section 101 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 is transferred to title V of the Public Health Service Act, inserted after the section 501 inserted by paragraph (2), redesignated as section 502, and amended—

(A) in subsection (a)—

(i) by striking out "this Act" the first time it occurs and inserting in lieu thereof "this section",

(ii) by striking out "assigned to the Secretary of Health and Human Services (hereafter in this Act referred to as the 'Secretary')" and inserting in lieu thereof "relating to alcohol abuse and alcoholism assigned to the Secretary", and

(iii) by striking out "of the Public Health Service Act", and

(B) by amending the section heading to read as follows:

"NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM".

(4) Section 501 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act is transferred to title V of the Public Health Service Act, inserted after the section 502 inserted by paragraph (3), redesignated as section 503, and amended—

(A) in subsection (a)—

(i) by inserting "SEC. 503." before "(a)",

(ii) by striking out "this title" and inserting in lieu thereof "this section",

(iii) by striking out "of the Secretary of Health and Human Services (hereinafter in this title referred to as the 'Secretary') with respect to drug abuse prevention functions" and inserting in lieu thereof "relating to drug abuse assigned to the Secretary by this Act", and

(iv) by striking out "of the Public Health Service Act",

(B) by striking out "(hereinafter in this title referred to as the 'Director')" in subsection (b)(1), and

(C) by striking out the section heading

"§ 501. Establishment of Institute".

and inserting in lieu thereof the following:

"NATIONAL INSTITUTE ON DRUG ABUSE".

(5) Subsection (a) of section 406 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act is transferred to section 503 (as so redesignated), inserted after subsection (d), and redesignated as subsection (e).

(6) Section 455 of the Public Health Service Act is inserted in title V of the Public Health Service Act after the section 503 inserted by paragraph (4) of this subsection and redesignated as section 504.

(7) The following sections are inserted in title V of the Public Health Service Act after the section 504 inserted by paragraph (6):

"REPORTS ON ALCOHOLISM, ALCOHOL ABUSE, AND DRUG ABUSE

"SEC. 505. (a) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

"(1) containing current information on the health consequences of using alcoholic beverages,

"(2) containing a description of current research findings made with respect to alcohol abuse and alcoholism, and

"(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

"(b) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

"(1) describing the health consequences and extent of drug abuse in the United States;

"(2) describing current research findings made with respect to drug abuse, including current findings on the health effects of marihuana and the addictive property of tobacco; and

"(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

"PEER REVIEW

"SEC. 506. (a) The Secretary, after consultation with the Directors of the National Institute of Mental Health, the National Institute on Alochol Abuse and Alcoholism, and the National Institute on Drug Abuse shall by regulation require appropriate technical and scientific peer review of biomedical and behavioral research and development grants, cooperative agreements, and contracts to be administered through the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse.

"(b) Regulations promulgated under subsection (a) shall require that the review of grants, cooperative agreements, and contracts required by the regulations be conducted—

"(1) in a manner consistent with the system for scientific peer review applicable on the date of the

enactment of this section to grants, cooperative agreements, and contracts under this Act for biomedical and behavioral research, and

"(2) to the extent practical, by peer review groups performing such review on or before such date.

"(c) The members of any peer review group established under such regulations shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group and not more than one-fourth of the members of any peer review group established under such regulations shall be officers or employees of the United States.

"(d) The Administrator of the administration shall establish procedures for periodic, technical, and scientific peer review of research at the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. Such procedures shall require that—

"(1) the reviewing entity be provided a written description of the research to be reviewed; and

"(2) the reviewing entity provide the advisory council of the institute involved with such description and the results of the review by the entity.".

(8) The following heading is inserted in title V of the Public Health Service Act after the section 506 inserted by paragraph (7):

"PART B—RESEARCH

"Subpart 1—Alcohol Abuse and Alcoholism".

(9) Sections 501, 503, and 504 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 are transferred to the

subpart 1 of Part B of title V of the Public Health Service Act established by paragraph (8), redesignated as sections 510, 511, and 512, respectively, and amended as follows:

(A) Section 510 (as so redesignated) is amended—

(i) by striking out "the Institute" in subsection (a) and inserting in lieu thereof "the National Institute on Alcohol Abuse and Alcoholism (hereinafter in this subpart referred to as the 'Institute')",

(ii) by striking out "make available through publications and other appropriate means" in subsection (b)(1) and inserting in lieu thereof "disseminate through publications and other appropriate means (including the development of curriculum materials)",

(iii) by striking "; and such Council shall give" and all that follows in subsection (b)(3) and inserting in lieu thereof the following ", giving special consideration to projects relating to—

"(A) the relationship between alcohol abuse and domestic violence,

"(B) the effects of alcohol use during pregnancy,

"(C) the impact of alcoholism and alcohol abuse on the family, the workplace, and systems for the delivery of health services,

"(D) the relationship between the abuse of alcohol and other drugs,

"(E) the effect on the incidence of alcohol abuse and alcoholism of social pressures, legal requirements respecting the use of alcoholic beverages, the cost of such beverages, and the economic status and education of users of such beverages,

"(F) the interrelationships between alcohol use and other health problems, and

"(G) the comparison of the cost and effectiveness of various treatment methods for alcoholism and alcohol abuse and the effectiveness of prevention and intervention programs for alcoholism and alcohol abuse.",

(iv) by inserting "or the impact of alcohol abuse on other health problems" before the semicolon in subsection (b)(5), and

(v) by amending the section heading to read as follows:

"ALCOHOL ABUSE AND ALCOHOLISM RESEARCH".

(B) Section 511 (as so redesignated) is amended—

(i) by striking out the last sentence of subsection (a),

(ii) by striking out the second sentence of subsection (b),

(iii) by striking out "of the Public Health Service Act (42 U.S.C. 292a)" in subsection (b), and

(iv) by striking out subsection (c).

(C) Section 512 (as so redesignated) is amended to read as follows:

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 512. There are authorized to be appropriated to carry out this subpart $33,484,000 for fiscal year 1983 and $45,790,000 for fiscal year 1984. Of the funds appropriated under this section for any fiscal year, not more than 35 per centum may be obligated for grants under section 511.".

(10) The following heading is inserted in title V of the Public Health Service Act after the section 512 inserted by paragraph (9):

"Subpart 2—Drug Abuse Research".

(11) Section 503 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act is transferred to the subpart 2 of part B of title V established by paragraph (10), redesignated as section 515, and amended—

(A) by striking out "The Director" the first time it occurs in subsection (a) and inserting in lieu thereof "The Director of the National Institute on Drug Abuse",

(B) by amending subsection (b) to read as follows:

"(b) In carrying out the activities described in subsection (a), the Secretary, acting through the Institute, may—

"(1) collect and disseminate through publications and other appropriate means, including the development of curriculum materials, information as to, and the practical application of, the research and other activities under this section,

"(2) make grants or enter into contracts with individuals and public and nonprofit entities for the purpose of determining the causes of drug abuse in a particular area, and

"(3) make grants to and enter into contracts with individuals and public and private nonprofit entities for research respecting improved drug maintenance and detoxification techniques and programs.",

(C) by amending subsection (c) to read as follows:

"(c) For the purposes of subsections (a) and (b), there are authorized to be appropriated $47,374,000 for fiscal year 1983 and $56,160,000 for fiscal year 1984.",

(D) by striking out the section heading and inserting in lieu thereof the following:

"DRUG ABUSE RESEARCH",

and

(E) by inserting before "(a)" in subsection (a) the following: "SEC. 515.".

(12) The following headings are inserted in title V of the Public Health Service Act after the section 515 inserted by paragraph (11):

"PART C—MISCELLANESOU PROVISIONS RELATING TO ALCOHOL ABUSE AND ALCOHOLISM AND DRUG ABUSE

"Subpart 1—Provisions Relating to Alcohol Abuse and Alcoholism".

(13) Sections 201, 301, 321, and 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treat-

ment, and Rehabilitation Act of 1970 are transferred to the part C of title V established by paragraph (12), redesignated as sections 520, 521, 522, and 523, respectively, and amended as follows:

(A) Section 520 (as so redesignated) is amended —

(i) by striking out "the Institute" in subsection (a) and inserting in lieu thereof "the National Institute on Alcohol Abuse and Alcoholism",

(ii) by striking out "section 321" in subsec- (a)(4) and inserting in lieu thereof "section 522", and

(iii) by striking out "under this Act and under the Drug Abuse Prevention, Treatment, and Rehabilitation Act" and inserting in lieu thereof "under this title".

(B) Section 521 (as so redesignated) is amended—

(i) by striking out "section 413(b) of the Drug Abuse Prevention, Treatment, and Rehabilitation Act" in subsection (b)(4) and inserting in lieu thereof "section 525",

(ii) by striking out "title" in subsection (d) and inserting in lieu thereof "section", and

(iii) by striking out subsection (e).

(C) Section 522 (as so redesignated) is amended by striking out "of the Public Health Service Act" in subsection (a).

(14) The following heading is inserted in part C of title V of the Public Health Service Act after section 523 (as so redesignated):

"Subpart 2—Provisions Relating to Drug Abuse".

(15) Section 502 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act is transferred to title V of the Public Health Service Act, inserted after the heading inserted by paragraph (14), redesignated as section 524, and amended—

(A) by striking out "The Director" in subsection (a) and inserting in lieu thereof "The Director of the National Institute on Drug Abuse",

(B) by striking out ", to promote the purposes of this Act," in subsection (b)(2),

(C) by striking out "section 407" in subsection (d) and inserting in lieu thereof "section 526",

(D) by striking out "under this Act and under the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970" in subsection (d) and inserting in lieu thereof "under this title",

(E) by striking out the section heading and inserting in lieu thereof:

"TECHNICAL ASSISTANCE TO STATE AND LOCAL AGENCIES",

and

(F) by inserting before "(a)" in subsection (a) the following: "SEC. 524.".

(16)(A) Section 413 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act is transferred to title V of the Public Health Service Act, inserted after the section 524 inserted by paragraph (15), redesignated as section 525, and amended—

(i) by striking out the section heading and inserting in lieu thereof:

"DRUG ABUSE AMONG GOVERNMENT AND OTHER EMPLOYEES";

(ii) by inserting before "(a)" the following: "SEC. 525."; and

(iii) by striking out "section 201(b) of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970" in subsection (b)(4) and inserting in lieu thereof "section 521".

(B) Section 407 and 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act are transferred to title V of the Public Health Service Act, inserted after the section 525 inserted by subparagraph (A), redesignated as sections 526 and 527 and amended as follows:

(i) Section 526 (as so redesignated) is amended—

(I) by striking out the section heading and inserting in lieu thereof:

"ADMISSION OF DRUG ABUSERS TO PRIVATE AND PUBLIC HOSPITALS";

and

(II) by inserting before "(a)" in subsection (a) the following: "SEC. 526.".

(ii) Section 527 (as so redesignated) is amended—

(I) by striking out the section heading and inserting in lieu thereof:

"CONFIDENTIALITY OF PATIENT RECORDS";

(II) by inserting before "(a)" in subsection (a) the following: "SEC. 527."; and

(III) by striking out "of Health and Human Services" in subsection (g).

(c)(1) Sections 102, 103, and 502 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 are repealed.

(2) Sections 405 and 504 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act are repealed.

(d) Title V of the Medical Facilities Construction and Modernization Amendments of 1970 (Public Law 91-296) is repealed.

ALCOHOL AND DRUG ABUSE AND MENTAL HEALTH REPORTS BY THE SECRETARY

SEC. 3. (a) The Secretary of Health and Human Services shall submit to the Congress on or before January 15, 1984, a report describing the extent to which Federal and State programs, departments, and agencies are concerned and are dealing effectively with—

(1) the problems of alcohol abuse and alcoholism,

(2) the problems of drug abuse, and

(3) mental illness.

(b) The report required by subsection (a) shall include information with respect to the services provided for alcohol abuse, alcoholism, drug abuse, and mental health under part B of title XIX of the Public Health Service Act. To obtain information respecting such services, the Secretary shall work with appropriate national organizations to en-

sure that State and local governments use compatible means of collecting data respecting such services so that uniform national data with respect to the provisions of such services will be available to the States and to the Secretary.

(c) In compiling data for the report required by subsection (a), the Secretary may not require any State to submit any information which is not required under section 1916 (a) of the Public Health Service Act.

DRUG ABUSE STRATEGY REPORT

SEC. 4. (a) Section 305 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1165) is amended to read as follows:

"§ 305. Report

"The President shall submit to the Congress on or before August 1, 1984, and every two years thereafter, a written report describing the strategy. The report shall specify the objectives, nature, and results of the strategy and shall contain an accounting of funds expended under title II.".

(b) Section 207 of such Act (21 U.S.C. 1117) is repealed.

MISCELLANEOUS

SEC. 5. (a)(1) Section 311(c)(4) of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4577(c)(4)) is amended by inserting "(including Native Hawaiians and Native American Pacific Islanders)" after "Native Americans".

(2) Section 18(b)(10) of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1979 (42 U.S.C. 4541

note) is amended by inserting "Native Hawaiians, Native American Pacific Islanders," after "Alaskan Natives,".

(3) Section 410(d) of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1177(d)) is amended by striking out "native Americans" and inserting in lieu thereof "Native Americans (including Native Hawaiians and Native American Pacific Islanders)".

(b) Section 475(a) of the Public Health Service Act (42 U.S.C. 2981-4(a)) is amended (1) by striking out "the Directors of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse and", and (2) by striking out ", the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse," in paragraph (2).

Approved April 26, 1983.

Public Law 98-474
98th Congress

An Act

To establish a national program to increase the availability of information on the health consequences of smoking, to amend the Federal Cigarette Labeling and Advertising Act to change the label requirements for cigarettes, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may be cited as the "Comprehensive Smoking Education Act".

PURPOSE

SEC. 2. It is the purpose of this Act to provide a new strategy for making Americans more aware of any adverse health effects of smoking, to assure the timely and widespread dissemination of research findings and to enable individuals to make informed decisions about smoking.

SMOKING RESEARCH, EDUCATION, AND INFORMATION

SEC. 3. (a) The Secretary of Health and Human Services (hereinafter in this section referred to as the "Secretary") shall establish and carry out a program to inform the public of any dangers to human health presented by cigarette smoking. In carrying out such program, the Secretary shall—

(1) conduct and support research on the effect of cigarette smoking on human health and develop materials for informing the public of such effect;

(2) coordinate all research and educational programs and other activities within the Department of Health and Human Services (hereinafter in this section referred to as the "Department") which relate to the effect of cigarette smoking on human health and coordinate, through the Interagency Committee on Smoking and Health (established under subsection (b)), such activities with similar activities of other Federal agencies and of private agencies;

(3) establish and maintain a liaison with appropriate private entities, other Federal agencies, and State and local public agencies respecting activities relating to the effect of cigarette smoking on human health;

(4) collect, analyze, and disseminate (through publications, bibliographies, and otherwise) information, studies, and other data relating to the effect of cigarette smoking on human health, and develop standards, criteria, and methodologies for improved information programs related to smoking and health;

(5) compile and make available information on State and local laws relating to the use and consumption of cigarettes; and

(6) undertake any other additional information and research activities which the Secretary determines necessary and appropriate to carry out this section.

(b)(1) To carry out the activities described in paragraphs (2) and (3) of subsection (a) there is established an Interagency Committee on Smoking and Health. The Committee shall be composed of—

(A) members appointed by the Secretary from appropriate institutes and agencies of the Depart-

ment, which may include the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, the Health Resources and Services Administration, and the Centers for Disease Control;

(B) at least one member appointed from the Federal Trade Commission, the Department of Education, the Department of Labor, and any other Federal agency designated by the Secretary, the appointment of whom shall be made by the head of the entity from which the member is appointed; and

(C) five members appointed by the Secretary from physicians and scientists who represent private entities involved in informing the public about the health effects of smoking.

The Secretary shall designate the chairman of the Committee.

(2) While away from their homes or regular places of business in the performance of services for the Committee, members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistance, in the manner provided by sections 5702 and 5703 of title 5 of the United States Code.

(3) The Secretary shall make available to the Committee such staff, information, and other assistance as it may require to carry out its activities effectively.

(c) The Secretary shall transmit a report to Congress not later than January 1, 1985, and biennially thereafter which shall contain—

(1) an overview and assessment of Federal activities undertaken to inform the public of the health

consequences of smoking and the extent of public knowledge of such consequences,

(2) a description of the Secretary's and Committee's activities under subsection (a),

(3) information regarding the activities of the private sector taken in response to the effects of smoking on health, and

(4) such recommendations as the Secretary may consider appropriate.

LABELS FOR CIGARETTES AND CIGARETTE ADVERTISING

SEC. 4. (a) Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

"LABELING

"SEC. 4. (a)(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

"SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

"SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

"SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

"SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

"(2) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised (other than through the use of outdoor billboards) within the United States any cigarette unless the advertising bears, in accordance with the requirements of this section, one of the following labels:

"SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

"SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

"SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

"SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

"(3) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised within the United States through the use of outdoor billboards any cigarette unless the advertising bears, in accordance with the requirements of this section, one of the following labels:

"SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, And Emphysema.

"SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Health Risks.

"SURGEON GENERAL'S WARNING: Pregnant Women Who Smoke Risk Fetal Injury And Premature Birth.

"SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

"(b)(1) Each label statement required by paragraph (1) of subsection (a) shall be located in the place label statements were placed on cigarette packages as of the date of the enactment of this subsection. The phrase 'Surgeon General's Warning' shall appear in capital letters and the size of all other letters in the label shall be the same as the size of such letters as of such date of enactment. All the letters in the label shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package.

"(2) The format of each label statement required by paragraph (2) of subsection (a) shall be the format required for label statements in cigarette advertising as of the date of the enactment of this subsection, except that the phrase 'Surgeon General's Warning' shall appear in capital letters, the area of the rectangle enclosing the label shall be 50 per centum larger in size with a corresponding increase in the size of the type in the label, the width of the rule forming the border around the label shall be twice that in effect on such date, and the label may be placed at a distance from the outer edge of the advertisement which is one-half the distance permitted on such date. Each label statement shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material in the advertisement.

"(3) The format and type style of each label statement required by paragraph (3) of subsection (a) shall be the format and type style required in outdoor billboard advertising as of the date of the enactment of this subsection. Each such label statement shall be printed in capital letters

of the height of the tallest letter in a label statement on outdoor advertising of the same dimension on such date of enactment. Each such label statement shall be enclosed by a black border which is located within the perimeter of the format required in outdoor billboard advertising of the same dimension on such date of enactment and the width of which is twice the width of the vertical element of any letter in the label statement within the border.

"(c) The label statements specified in paragraphs (1), (2), and (3) of subsection (a) shall be rotated by each manufacturer or importer of cigarettes quarterly in alternating sequence on packages of each brand of cigarettes manufactured by the manufacturer or importer and in the advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer or importer and approved by the Federal Trade Commission. The Federal Trade Commission shall approve a plan submitted by a manufacturer or importer of cigarettes which will provide the rotation required by this subsection and which assures that all of the labels required by paragraphs (1), (2), and (3) will be displayed by the manufacturer or importer at the same time.

"(d) Subsection (a) does not apply to a distributor or a retailer of cigarettes who does not manufacture, package, or import cigarettes for sale or distribution within the United States.".

(b) The amendment made by subsection (a) shall take effect upon the expiration of a one-year period beginning on the date of the enactment of this Act.

CIGARETTE INGREDIENTS

SEC. 5. (a) The Federal Cigarette Labeling and Advertising Act is amended by redesignating sections 7 through

12 as sections 8 through 13, respectively, and by inserting after section 6 the following new section:

"CIGARETTE INGREDIENTS

"SEC. 7. (a) Each person who manufactures, packages, or imports cigarettes shall annually provide the Secretary with a list of the ingredients added to tobacco in the manufacture of cigarettes which does not identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients. A person or group of persons required to provide a list by this subsection may designate an individual or entity to provide the list required by this subsection.

"(b)(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a), respecting—

"(A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of cigarettes and the findings of such research;

"(B) information pertaining to any such ingredient which in the judgment of the Secretary poses a health risk to cigarette smokers; and

"(C) any other information which the Secretary determines to be in the public interest.

"(2)(A) Any information provided to the Secretary under subsection (a) shall be treated as trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code and section 1905 of title 18, United States Code and shall not be revealed, except as provided in paragraph (1), to any person other than those

authorized by the Secretary in carrying out their official duties under this section.

"(B) Subparagraph (A) does not authorize the withholding of a list provided under subsection (a) from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide it such a list, the Secretary shall make the list available to the subcommittee or committtee and shall, at the same time, notify in writing the person who provided the list of such request.

"(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a). Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

"(i) shall take physical possession of the information and, when not in use by a person authorized to have access to such information, shall store it in a locked cabinet or file, and

"(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.".

(b) Section 7 of the Federal Cigarette Labeling and Advertising Act added by subsection (a) shall take effect upon the expiration of the one-year period beginning on the date of the enactment of this Act.

MISCELLANEOUS AMENDMENTS

SEC. 6 (a) Paragraph (1) of section 2 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331) is amended to read as follows:

"(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and".

(b) Section 3 of such Act (15 U.S.C. 1332) is amended by adding at the end of the following:

"(8) The term 'Secretary' means the Secretary of Health and Human Services.".

(c) Section 8 of such Act (15 U.S.C. 1336) (as so redesignated) is amended to read as follows:

"FEDERAL TRADE COMMISSION

"SEC. 8. Nothing in this Act (other than the requirements of section 4(b)) shall be construed to limit, restrict, expand, or otherwise affect the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes.".

(d) Section 9 of such Act (15 U.S.C. 1337) (as so redesignated) is amended—

(1) by striking out "of Health, Education, and Welfare" in subsection (a),

(2) by redesignating clauses (A) and (B) in such subsection as clauses (1) and (2), respectively,

(3) by striking out clause (A) in subsection (b) and by redesignating clauses (B) and (C) as clauses (1) and (2), respectively.

Approved October 12, 1984.

Public Law 99-252
99th Congress

An Act

To provide for public education concerning the health consequences of using smokeless tobacco products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Comprehensive Smokeless Tobacco Health Education Act of 1986".

SEC. 2. PUBLIC EDUCATION.

(a) DEVELOPMENT.—(1) The Secretary of Health and Human Services shall establish and carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products. In carrying out such program the Secretary shall—

(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

(B) make such programs, materials, and announcements available to States, local governments, school systems, the media, and such other entities as the Secretary determines appropriate to further the purposes of this Act;

(C) conduct and support research on the effect of smokeless tobacco on human health; and

(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health.

(2) In developing programs, materials, and announcements under paragraph (1) the Secretary shall consult

with the Secretary of Education, medical and public health entities, consumer groups, representatives of manufacturers of smokeless tobacco products, and other appropriate entities.

(b) ASSISTANCE.—The Secretary of Health and Human Services may provide technical assistance and may make grants to States—

(1) to assist in the development of educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco,

(2) to assist in the distribution of such programs, materials, and announcements throughout the States, and

(3) to establish 18 as the minimum age for the purchase of smokeless tobacco.

SEC. 3. SMOKELESS TOBACCO WARNING.

(a) GENERAL RULE.—

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

"WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER
"WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS
"WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES".

(2) It shall be unlawful for any manufacturer, packager, or importer of smokeless tobacco prod-

ucts to advertise or cause to be advertised (other than through the use of outdoor billboard advertising) within the United States any smokeless tobacco product unless the advertising bears, in accordance with the requirements of this Act, one of the labels required by paragraph (1).

(b) LABEL FORMAT.—The Federal Trade Commission shall issue regulations requiring the label statement required by subsection (a) to appear—

(1) in the case of the smokeless tobacco product package—

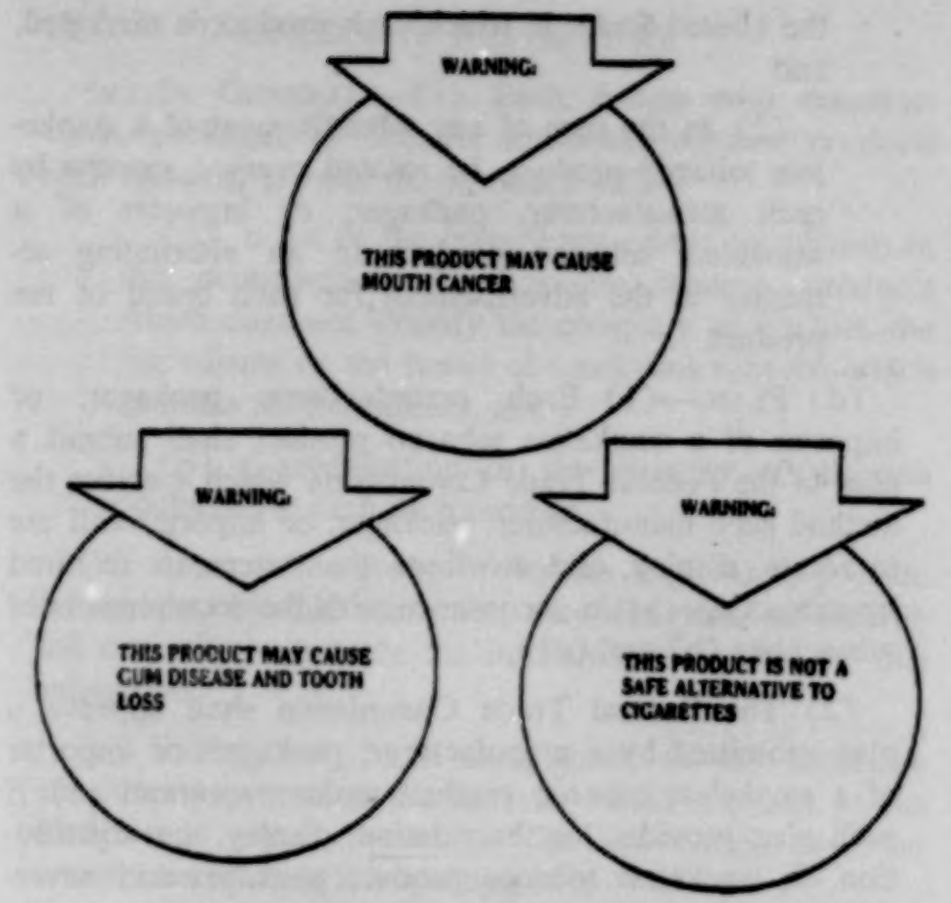
(A) in a conspicuous and prominent place on the package, and

(B) in a conspicuous format and in conspicuous and legible type in contrast with all other printed material on the package, and

(2) in the case of advertising subject to subsection (a)(2)—

(A) in a conspicuous and prominent location in the advertisement and in conspicuous and legible type in contrast with all other printed material in the advertisement,

(B) in the following format:



(C) the label statement shall appear in capital letters and the area of the circle and arrow shall be determined by the Federal Trade Commission.

(c) LABEL DISPLAY.—The Federal Trade Commission shall issue regulations requiring each label statement required by subsection (a) to—

(1) in the case of a smokeless tobacco product package, be randomly displayed by each manufacturer, packager, or importer of a smokeless tobacco product in each 12-month period in as equal a number of times as is possible on each brand of the product and be randomly distributed in all parts of

the United States in which such product is marketed, and

(2) in the case of any advertisement of a smokeless tobacco product, be rotated every 4 months by each manufacturer, packager, or importer of a smokeless tobacco product in an alternating sequence in the advertisement for each brand of the product.

(d) PLAN.—(1) Each manufacturer, packager, or importer of a smokeless tobacco product shall submit a plan to the Federal Trade Commission which specifies the method such manufacturer, packager, or importer will use to rotate, display, and distribute the statements required by subsection (a) in accordance with the requirements of subsections (b) and (c).

(2) The Federal Trade Commission shall approve a plan submitted by a manufacturer, packager, or importer of a smokeless tobacco product under paragraph (1) if such plan provides for the rotation, display, and distribution on smokeless tobacco product packages and advertisements of the statements required by subsection (a) in a manner which complies with this section and the regulations promulgated pursuant to this section.

(e) APPLICATION.—This section does not apply to a distributor or a retailer of any smokeless tobacco product which does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

(f) TELEVISION AND RADIO ADVERTISING.—Effective 6 months after the date of the enactment of this Act, it shall be unlawful to advertise smokeless tobacco on any medium of electronic communications subect to the jurisdiction of the Federal Communications Commission.

SEC. 4. INGREDIENT REPORTING.

(a) IN GENERAL.—(1) Each person who manufactures, packages, or imports smokeless tobacco products shall annually provide the Secretary with—

(A) a list of the ingredients added to tobacco in the manufacture of smokeless tobacco products which does not identify the company which uses the ingredients or the brand of smokeless tobacco which contains the ingredients; and

(B) a specification of the quantity of nicotine contained in each such product.

(2) A person or group of persons required to provide information by this subsection may designate an individual or entity to provide the information required by this subsection.

(b) REPORT.—(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a), respecting—

(A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of smokeless tobacco products and the findings of such research;

(B) information pertaining to any such ingredient which in the judgment of the Secretary poses a health risk to users of smokeless tobacco; and

(C) any other information which the Secretary determines to be in the public interest.

(2)(A) Any information provided to the Secretary under subsection (a) shall be treated as a trade secret or confidential information subject to section 552(b)(4) of

title 5, United States Code, and shall not be revealed, except as provided in paragraph (1), to any person other than those authorized by the Secretary in carrying out their official duties under this section.

(B) Subparagraph (A) does not authorize the withholding of information provided under subsection (a) of this section from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide it such information, the Secretary shall make the information available to the subcommittee or committee and shall, at the same time, notify in writing the person who provided the information of such request.

(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a) of this section. Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

(i) shall take physical possession of the information and, when not in use by any person authorized to have access to such information, shall store it in a locked cabinet or file; and

(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.

SEC. 5. ENFORCEMENT, REGULATIONS, AND CONSTRUCTION.

(a) ENFORCEMENT.—(1) A violation of section 3 or the regulations promulgated pursuant to this Act shall be

considered a violation of section 5 of the Federal Trade Commission Act.

(2) Any person who is found to violate any provision of section 3 or 4(a) shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than $10,000.

(b) REGULATIONS UNDER SECTION 3.—(1) Regulations issued by the Federal Trade Commission under section 3 shall be issued in accordance with section 553 of title 5, United States Code.

(2) Not later than 180 days after the date of the enactment of this Act, the Federal Trade Commission shall promulgate such regulations as it may require to implement section 3.

(c) CONSTRUCTION.—Nothing in this Act (other than the requirements of sections 3 and 4) shall be construed to limit, restrict, or expand the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of smokeless tobacco products.

SEC. 6. INJUNCTIONS.

The several district courts of the United States are vested with jurisdiction, for cause shown, to prevent and restrain violations of sections 3 and 4 upon application of the Federal Trade Commission in the case of a violation of section 3 or upon application of the Attorney General of the United States acting through the several United States attorneys in their several districts in the case of a violation of section 3 or 4.

SEC. 7. PREEMPTION.

(a) FEDERAL ACTION.—No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 3, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

(b) STATE AND LOCAL ACTION.—No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 3, shall be required by any State or local statute or regulation to be included on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

(c) EFFECT ON LIABILITY LAW.—Nothing in this Act shall relieve any person from liability at common law or under State statutory law to any other person.

SEC. 8. REPORTS.

(a) SECRETARY'S REPORT.—The Secretary of Health and Human Services shall transmit a report to the Congress not later than January 11, 1987, and biennially thereafter, containing—

(1) a description of the effects of health education efforts on the use of smokeless tobacco products,

(2) a description of the use by the public of smokeless tobacco products,

(3) an evaluation of the health effects of smokeless tobacco products and the identification of areas appropriate for further research, and

(4) such recommendations for legislation and administrative action as the Secretary considers appropriate.

(b) FTC REPORT.—The Federal Trade Commission shall transmit a report to the Congress not later than January 11, 1987, and biennially thereafter, containing (1) a description of the current sales, advertising, and marketing practices associated with smokeless tobacco products, and (2) such recommendations for legislation and administrative action as it deems appropriate.

SEC. 9. DEFINITIONS.

For purposes of this Act:

(1) The term "smokeless tobacco" means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity.

(2) The term "commerce" means (A) commerce between any state, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island.

(3) The term "United States", when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico,

Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Island, and installations of the Armed Forces.

(4) The term "package" means a pack, box, carton, pouch, or container of any kind in which smokeless tobacco products are offered for sale, sold, or otherwise distributed to consumers.

(5) The term "sale or distribution" includes sampling or any other distribution not for sale.

(6) The term "Secretary" means the Secretary of Health and Human Services.

SEC. 10. TECHNICAL AMENDMENT.

Section 402(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(d)(2)) is amended by inserting before the semicolon a comma and the following: "except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale".

SEC. 11. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided in sections 3(f) and 5(b) and subsection (b), this Act shall take effect one year after the date of enactment of this Act.

(b) EXCEPTION.—Sections 2, 3(b), 3(c), 3(d), 3(e), 4(b), 7, 8, 9, and 10 shall take effect on the date of the enactment of this Act.

Approved February 27, 1986.

Public Law 102-321
102d Congress

An Act

To amend the Public Health Service Act to restructure the Alcohol, Drug Abuse, and Mental Health Administration and the authorities of such Administration, including establishing separate block grants to enhance the delivery of services regarding substance abuse and mental health, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

* * * *

TITLE II—BLOCK GRANTS TO STATES REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE

* * * *

SEC. 202. ESTABLISHMENT OF SEPARATE BLOCK GRANT REGARDING SUBSTANCE ABUSE.

Part B of title XIX of the Public Health Service Act, as amended by section 201 of this Act, is amended by adding at the end the following:

"Subpart II—Block Grants for Prevention and Treatment of Substance Abuse

* * * *

"SEC. 1926. STATE LAW REGARDING SALE OF TOBACCO PRODUCTS TO INDIVIDUALS UNDER AGE OF 18.

"(a) RELEVANT LAW.—

"(1) IN GENERAL.—Subject to paragraph (2), for fiscal year 1994 and subsequent fiscal years, the

Secretary may make a grant under section 1921 only if the State involved has in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18.

"(2) DELAYED APPLICABILITY FOR CERTAIN STATES.—In the case of a State whose legislature does not convene a regular session in fiscal year 1993, and in the case of a State whose legislature does not convene a regular session in fiscal year 1994, the requirement described in paragraph (1) as a condition of a receipt of a grant under section 1921 shall apply only for fiscal year 1995 and subsequent fiscal years.

"(b) ENFORCEMENT.—

"(1) IN GENERAL.—For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section 1921 is that the State involved will enforce the law described in subsection (a) in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18.

"(2) ACTIVITIES AND REPORTS REGARDING ENFORCEMENT.—For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section 1921 is that the State involved will—

"(A) annually conduct random, unannounced inspections to ensure compliance with the law described in subsection (a); and

"(B) annually submit to the Secretary a report describing—

"(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

"(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18; and

"(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

"(c) NONCOMPLIANCE OF STATE.—Before making a grant under section 1921 to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (a) and (b). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under such section for the State for the fiscal year involved by an amount equal to—

"(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 1933 for the State for the fiscal year;

"(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 1933 for the State for the fiscal year;

"(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 1933 for the State for the fiscal year; and

"(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount

determined under section 1933 for the State for the fiscal year.

"(d) DEFINITION.—For purposes of this section, the term 'first applicable fiscal year' means—

"(1) fiscal year 1995, in the case of any State described in subsection (a)(2); and

"(2) fiscal year 1994, in the case of any other State.

UNITED STATES CODE
TITLE 15. COMMERCE AND TRADE
CHAPTER 36—CIGARETTE LABELING AND ADVERTISING

Sec. 1331. Congressional declaration of policy and purpose

It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and

(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

Sec. 1332. Definitions

As used in this chapter—

(1) The term "cigarette" means—

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and

(B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

(2) The term "commerce" means (A) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any state, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island.

(3) The term "United States", when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term "State" includes any political division of any State.

(4) The term "package" means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

(5) The term "person" means an individual, partnership, corporation, or any other business or legal entity.

(6) The term "sale or distribution" includes sampling or any other distribution not for sale.

(7) The term "little cigar" means any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of subsection (1) of this section) and as to which one thousand units weigh not more than three pounds.

(8) The term "brand style" means a variety of cigarettes distinguished by the tobacco used, tar and nicotine content, flavoring used, size of the cigarette, filtration on the cigarette, or packaging.

(9) The term "Secretary" means the Secretary of Health and Human Services.

Sec. 1333. Labeling; requirements; conspicuous statestatement

(a) Required warnings; packages; advertisement; billboards

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

(2) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised (other than through the use of outdoor billboards) within the United States any cigarette unless the advertising bears,

in accordance with the requirements of this section, one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

(3) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised within the United States through the use of outdoor billboards any cigarette unless the advertising bears, in accordance with the requirements of this section, one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, and Emphysema.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Health Risks.

SURGEON GENERAL'S WARNING: Pregnant Women Who Smoke Risk Fetal Injury And Premature Birth.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

(b) Conspicuous statement; label statement format; outdoor billboard statement format

(1) Each label statement required by paragraph (1) of subsection (a) of this section shall be located in the place label statements were placed on cigarette packages as of October 12, 1984. The phrase "Surgeon General's Warning" shall appear in capital letters and the size of all other letters in the label shall be the same size of such letters as of October 12, 1984. All the letters in the label shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package.

(2) The format of each label statement required by paragraph (2) of subsection (a) of this section shall be the format required for label statements in cigarette advertising as of October 12, 1984, except that the phrase "Surgeon General's Warning" shall appear in capital letters, the area of the rectangle enclosing the label shall be 50 per centum larger in size with a corresponding increase in size of the type in the label, the width of the rule forming the border around the label shall be twice that in effect on October 12, 1984, and the label may be placed at a distance from the outer edge of the advertisement which is one-half the distance permitted on October 12, 1984. Each label statement shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material in the advertisement.

(3) The format and type style of each label statement required by paragraph (3) of subsection (a) of this section shall be the format and type style required in outdoor billboard advertising as of October 12, 1984. Each such label statement shall be printed in capital letters of the height of the tallest letter in a label statement on outdoor advertising of the same dimension on October 12, 1984.

Each such label statement shall be enclosed by a black border which is located within the perimeter of the format required in outdoor billboard advertising of the same dimension on October 12, 1984, and the width of which is twice the width of the vertical element of any letter in the statement within the border.

(c) Rotation of label statement; plan; submission to Federal Trade Commission

(1) Except as provided in paragraph (2), the label statements specified in paragraphs (1), (2), and (3) of subsection (a) of this section shall be rotated by each manufacturer or importer of cigarettes quarterly in alternating sequence on packages of each brand of cigarettes manufactured by the manufacturer or importer and in the advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer or importer and approved by the Federal Trade Commission. The Federal Trade Commission shall approve a plan submitted by a manufacturer or importer of cigarettes which will provide the rotation required by this subsection and which assures that all of the labels required by paragraphs (1), (2), and (3) will be displayed by the manufacturer or importer at the same time.

(2)(A) A manufacturer or importer of cigarettes may apply to the Federal Trade Commission to have the label rotation described in subparagraph (C) apply with respect to a brand style of cigarettes manufactured or imported by such manufacturer or importer if—

(i) the number of cigarettes of such brand style sold in the fiscal year of the manufacturer or importer preceding the submission of the application is less than one-fourth of 1 percent of all the cigarettes sold in the United States in such year, and

(ii) more than one-half of the cigarettes manufactured or imported by such manufacturer or importer for sale in the United States are packaged into brand styles which meet the requirements of clause (i).

If an application is approved by the Commission, the label rotation described in subparagraph (C) shall apply with respect to the applicant during the one year period beginning on the date of the application approval.

(B) An applicant under subparagraph (A) shall include in its application a plan under which the label statements specified in paragraph (1) of subsection (a) of this section will be rotated by the applicant manufacturer or importer in accordance with the label rotation described in subparagraph (C).

(C) Under the label rotation which a manufacturer or importer with an approved application may put into effect each of the labels specified in paragraph (1) of subsection (a) of this section shall appear on the packages of each brand style of cigarettes with respect to which the application was approved an equal number of times within the twelve-month period beginning on the date of the approval by the Commission of the application.

(d) Application; distributors; retailers

Subsection (a) of this section does not apply to a distributor or a retailer of cigarettes who does not manufacture, package, or import cigarettes for sale or distribution within the United States.

Sec. 1334. Preemption

(a) Additional statements

No statement relating to smoking and health, other than the statements required by section 1333 of this title, shall be required on any cigarette package.

(b) State regulations

No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

Sec. 1335. Unlawful advertisements on medium of electronic communication

After January 1, 1971, at shall be unlawful to advertise cigarettes and little cigars on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission.

Sec. 1335a. List of cigarette ingredients; annual submission to Secretary; transmittal to Congress; confidentiality

(a) Each person who manufactures, packages, or imports cigarettes shall annually provide the Secretary with a list of the ingredients added to tobacco in the manufacture of cigarettes which does not identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients. A person or group of persons required to provide a list by this subsection may designate an individual or entity to provide the list required by this subsection.

(b)(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a) of this section, respecting—

(A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of cigarettes and the findings of such research;

(B) information pertaining to any such ingredient which in the judgement[1] of the Secretary poses a health risk to cigarette smokers; and

(C) any other information which the Secretary determines to be in the public interest.

(2)(A) Any information provided to the Secretary under subsection (a) of this section shall be treated as trade secret or confidential information subject to section 552(b)(4) of title 5 and section 1905 of title 18 and shall not be revealed, except as provided in paragraph (1), to any person other than those authorized by the Secretary in carrying out their official duties under this section.

(B) Subparagraph (A) does not authorize the withholding of a list provided under subsection (a) of this section from any duly authorized subcommittee or commitee of the Congress. If a subcommittee or committee of the Congres requests the Secretary to provide it such a list, the Secretary shall make the list available to the subcommittee or commitee and shall, at the same time, notify in writing the person who provided the list of such request.

(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a) of this section. Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

(i) shall take physical possession of the information and, when not in use by a person authorized to have access to such information, shall store it in a locked cabinet or file, and

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1 So in original. Probably should be "judgment".

(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.

Sec. 1336. Authority of Federal Trade Commission; unfair or deceptive acts or practices

Nothing in this chapter (other than the requirements of section 1333 of this title) shall be construed to limit, restrict, expand, or otherwise affect the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes.

Sec. 1337. Reports to Congress by the Secretary and Federal Trade Commission

(a) The Secretary shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter, concerning (1) current information in the health consequences of smoking, and (2) such recommendations for legislation as he may deem appropriate.

(b) The Federal Trade Commission shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter, concerning (1) current practices and methods of cigarette advertising and promotion, and (2) such recommendations for legislation as it may deem appropriate.

Sec. 1338. Criminal penalty

Any person who violates the provisions of this chapter shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than $10,000.

Sec. 1339. Injunction proceedings

The several district courts of the United States are invested with jurisdiction, for cause shown, to prevent and restrain violations of this chapter upon the application of the Attorney General of the United States acting through the several United States attorneys in their several districts.

Sec. 1340. Cigarettes for export

Packages of cigarettes manufactured, imported, or packaged (1) for export from the United States or (2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the United States shall be exempt from the requirements of this chapter, but such exemptions shall not apply to cigarettes manufactured, imported, or packaged for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

Sec. 1341. Smoking, research, education and information

(a) Establishment of program; Secretary; functions

The Secretary of Health and Human Services (hereinafter in this section referred to as the "Secretary") shall establish and carry out a program to inform the public of any dangers to human health presented by cigarette smoking. In carrying out such program, the Secretary shall—

(1) conduct and support research on the effect of cigarette smoking on human health and develop materials for informing the public of such effect;

(2) coordinate all research and educational programs and other activities within the Department of Health and Human Services (hereinafter in this section referred to as the "Department") which relate

to the effect of cigarette smoking on human health and coordinate, through the Interagency Committee on Smoking and Health (established under subsection (b) of this section), such activities with similar activities of other Federal agencies and of private agencies;

(3) establish and maintain a liaison with appropriate private entities, other Federal agencies, and State and local public agencies respecting activities relating to the effect of cigarette smoking on human health;

(4) collect, analyze, and disseminate (through publications, bibliographies, and otherwise) information, studies, and other data relating to the effect of cigarette smoking on human health, and develop standards, criteria, and methodolgies for improved information programs related to smoking and health;

(5) compile and make available information on State and local laws relating to the use and consumption of cigarettes; and

(6) undertake any other additional information and research activities which the Secretary determines necessary and appropriate to carry out this section.

(b) Interagency Committee on Smoking and Health; composition; chairman; compensation; staffing and other assistance

(1) To carry out the activities described in paragraphs (2) and (3) of subsection (a) of this section there is established an Interagency Committee on Smoking and Health. The Committee shall be composed of—

(A) members appointed by the Secretary from appropriate institutes and agencies of the Department, which may include the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, the Health Resources and Services Administration, and the Centers for Disease Control and Prevention;

(B) at least one member appointed from the Federal Trade Commission, the Department of Educaton, the Department of Labor, and any other Federal agency designated by the Secretary, the appointment of whom shall be made by the head of the entity from which the member is appointed; and

(C) five members appointed by the Secretary from physicians and scientists who represent private entities involved in informing the public about the health effects of smoking.

The Secretary shall designate the chairman of the Committee.

(2) While away from their homes or regular places of business in the performance of services for the Committee, members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistance,[1] in the manner provided by sections 5702 and 5703 of title 5.

(3) The Secretary shall make available to the Committee such staff, information, and other assistance as it may require to carry out its activities effectively.

(c) Report to Congress; contents

The Secretary shall transmit a report to Congress not later than January 1, 1986, and biennially thereafter which shall contain—

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[1] So in original. Probably should be "subsistence,".

(1) an overview and assessment of Federal activities undertaken to inform the public of the health consequences of smoking and the extent of public knowledge of such consequences,

(2) a description of the Secretary's and Committee's activities under subsection (a) of this section,

(3) information regarding the activities of the private sector taken in response to the effects of smoking on health, and

(4) such recommendations as the Secretary may consider appropriate.

CHAPTER 70—COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION

Sec. 4401. Public education

(a) Development

(1) The Secretary of Health and Human Services shall establish and carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products. In carrying out such program the Secretary shall—

(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

(B) make such programs, materials, and announcements available to States, local governments, school systems, the media, and such other entities as the Secretary determines appropriate to further the purposes of this chapter;

(C) conduct and support research on the effect of smokeless tobacco on human health; and

(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health.

(2) In developing programs, materials, and announcements under paragraph (1)[1] the Secretary shall consult with the Secretary of Education, medical and public health entities, consumer groups, representatives of manufacturers of smokeless tobacco products, and other appropriate entities.

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[1] So in original. Probably should be followed by a comma.

(b) Assistance

The Secretary of Health and Human Services may provide technical assistance and may make grants to States—

(1) to assist in the development of educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco,

(2) to assist in the distribution of such programs, materials, and announcements throughout the States, and

(3) to establish 18 as the minimum age for the purchase of smokeless tobacco.

Sec. 4402. Smokeless tobacco warning

(a) General rule

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this chapter, one of the following labels:

"WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER

"WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS

"WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES".

(2) It shall be unlawful for any manufacturer, packager, or importer of smokeless tobacco products to advertise or cause to be advertised (other than through the use of outdoor billboard advertising) within the United States any smokeless tobacco product unless the advertising bears, in

accordance with the requirements of this chapter, one of the labels required by paragraph (1).

(b) Label format

The Federal Trade Commission shall issue regulations requiring the label statement required by subsection (a) of this section to appear—

(1) in the case of the smokeless tobacco product package—

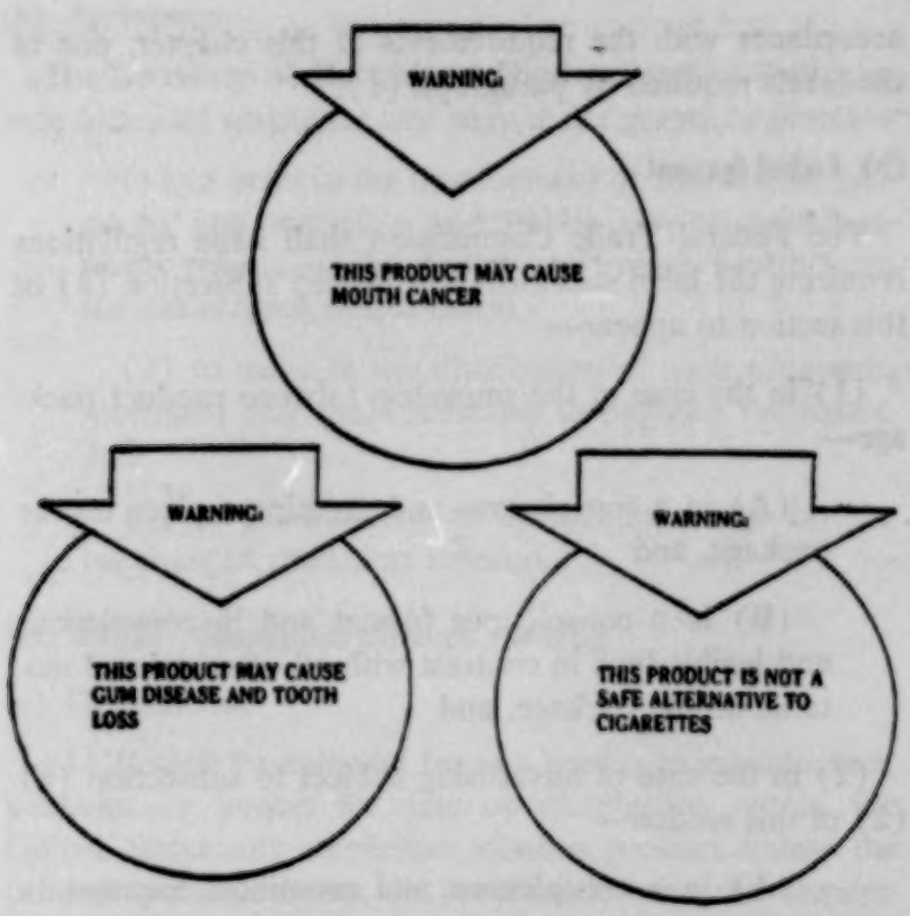
(A) in a conspicuous and prominent place on the package, and

(B) in a conspicuous format and in conspicuous and legible type in contrast with all other printed material on the package, and

(2) in the case of advertising subject to subsection (a)(2) of this section—

(A) in a conspicuous and prominent location in the advertisement and in conspicuous and legible type in contrast with all other printed material in the advertisement,

(B) in the following format:



(C) the label statement shall appear in capital letters and the area of the circle and arrow shall be determined by the Federal Trade Commission.

(c) Label display

The Federal Trade Commission shall issue regulations requiring each label statement required by subsection (a) of this section to—

(1) in the case of a smokeless tobacco product package, be randomly displayed by each manufacturer, packager, or importer of a smokeless tobacco product in each 12-month period in as equal a number of times as is possible on each brand of the product and be randomly distributed in all parts of the United States in which such product is marked, and

(2) in the case of any advertisement of a smokeless tobacco product, be rotated every 4 months by each manufacturer, packager, or importer of a smokeless tobacco product in an alternating sequence in the advertisement for each brand of the product.

(d) Plan

(1) Each manufacturer, packager, or importer of a smokeless tobacco product shall submit a plan to the Federal Trade Commission which specifies the method such manufacturer, packager, or importer will use to rotate, display, and distribute the statements required by subsection (a) of this section in accordance with the requirements of subsections (b) and (c) of this section.

(2) The Federal Trade Commission shall approve a plan submitted by a manufacturer, packager, or importer of a smokeless tobacco product under paragraph (1) if such plan provides for the rotation, display, and distribution on smokeless tobacco product packages and advertisements of the statements required by subsection (a) of this section in a manner which complies with this section and the regulations promulgated pursuant to this section.

(e) Application

This section does not apply to a distributor or a retailer of any smokeless tobacco product which does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

(f) Television and radio advertising

Effective 6 months after February 27, 1986, it shall be unlawful to advertise smokeless tobacco on any medium of

electronic communications subject to the jurisdiction of the Federal Communications Commission.

Sec. 4403. Ingredient reporting

(a) In general

(1) Each person who manufactures, packages, or imports smokeless tobacco products shall annually provide the Secretary with—

(A) a list of the ingredients added to tobacco in the manufacture of smokeless tobacco products which does not identify the company which uses the ingredients or the brand of smokeless tobacco which contains the ingredients; and

(B) a specification of the quantity of nicotine contained in each such product.

(2) A person or group of persons required to provide information by this subsection may designate an individual or entity to provide the information required by this subsection.

(b) Report

(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a) of this section, respecting—

(A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of smokeless tobacco products and the findings of such research;

(B) information pertaining to any such ingredient which in the judgment of the Secretary poses a health risk to users of smokeless tobacco; and

(C) any other information which the Secretary determines to be in the public interest.

(2)(A) Any information provided to the Secretary under subsection (a) of this section shall be treated as a trade secret or confidential information subject to section 552(b)(4) of title 5 and shall not be revealed, except as provided in paragraph (1), to any person other than those authorized by the Secretary in carrying out their official duties under this section.

(B) Subparagraph (A) does not authorize the withholding of information provided under subsection (a) of this section from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide it such information, the Secretary shall make the information available to the subcommittee or committee and shall, at the same time, notify in writing the person who provided the information of such request.

(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a) of this section. Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

(i) shall take physical possession of the information and, when not in use by any person authorized to have access to such information, shall store it in a locked cabinet or file; and

(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.

Sec. 4404. Enforcement, regulation, and construction

(a) Enforcement

(1) A violation of section 4402 of this title or the regulations promulgated pursuant to this chapter shall be considered a violation of section 45 of this title.

(2) Any person who is found to violate any provision of section 4402 or 4403(a) of this title shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than $10,000.

(b) Regulations under section 4402 of this title

(1) Regulations issued by the Federal Trade Commission under section 4402 of this title shall be issued in accordance with section 553 of title 5.

(2) Not later than 180 days after February 27, 1986, the Federal Trade Commission shall promulgate such regulations as it may require to implement section 4402 of this title.

(c) Construction

Nothing in this chapter (other than the requirements of sections 4402 and 4403 of this title) shall be construed to limit, restrict, or expand the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of smokeless tobacco products.

Sec. 4405. Injunctions

The several district courts of the United States are vested with jurisdiction, for cause shown, to prevent and restrain violations of sections 4402 and 4403 of this title upon application of the Federal Trade Commission in the case of a violation of section 4402 of this title, or upon application of the Attorney General of the United States acting through the several United States attorneys in their

several districts in the case of a violation of section 4402 or 4403 of this title.

Sec. 4406. Preemption

(a) Federal action

No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

(b) State and local action

No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any State or local statute or regulation to be included on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

(c) Effect on liability law

Nothing in this chapter shall relieve any person from liability at common law or under State statutory law to any other person.

Sec. 4407. Reports

(a) Secretary's report

The Secretary of Health and Human Services, shall transmit a report to the Congress not later than January 11, 1987, and biennially thereafter, containing—

(1) a description of the effects of health education efforts on the use of smokeless tobacco products,

(2) a description of the use by the public of smokeless tobacco products,

(3) an evaluation of the health effects of smokeless tobacco products and the identification of areas appropriate for further research, and

(4) such recommendations for legislation and administrative action as the Secretary considers appropriate.

(b) FTC report

The Federal Trade Commission shall transmit a report to the Congress not later than January 11, 1987, and biennially thereafter, containing (1) a description of the current sales, advertising, and marketing practices associated with smokeless tobacco products, and (2) such recommendations for legislation and administrative action as it deems appropriate.

Sec. 4408. Definitions

For purposes of this chapter:

(1) The term "smokeless tobacco" means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity.

(2) The term "commerce" means (A) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island.

(3) The term "United States", when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Island, and installations of the Armed Forces.

(4) The term "package" means a pack, box, carton, pouch, or container of any kind in which smokeless tobacco products are offered for sale, sold, or otherwise distributed to consumers.

(5) The term "sale or distribution" includes sampling or any other distribution not for sale.

(6) The term "Secretary" means the Secretary of Health and Human Services.

TITLE 20. EDUCATION
CHAPTER 68—NATIONAL EDUCATION REFORM
SUBCHAPTER X—MISCELLANEOUS
PART B—ENVIRONMENTAL TOBACCO SMOKE

Sec. 6083. Nonsmoking policy for children's services

(a) Prohibition

After March 31, 1994, no person shall permit smoking within any indoor facility owned or leased or contracted for and utilized by such person for provision of routine or regular kindergarten, elementary, or secondary education or library services to children.

(b) Additional prohibition

After March 31, 1994, no person shall permit smoking within any indoor facility (or portion thereof) owned or leased or contracted for by such person for the provision by such person of regular or routine health care or day care or early childhood development (Head Start) services to children or for the use of the employees of such person who provides such services, except that this subsection shall not apply to—

(1) any portion of such facility that is used for inpatient hospital treatment of individuals dependent on, or addicted to, drugs or alcohol; and

(2) any private residence.

(c) Federal agencies

(1) Kindergarten, elementary, or secondary education or library services

After March 31, 1994, no Federal agency shall permit smoking within any indoor facility in the United

States operated by such agency, directly or by contract, to provide routine or regular kindergarten, elementary, or secondary education or library services to children.

(2) Health or day care or early childhood development services

After March 31, 1994, no Federal agency shall permit smoking within any indoor facility (or portion thereof) operated by such agency, directly or by contract, to provide routine or regular health or day care or early childhood development (Head Start) services to children, except that this paragraph shall not apply to—

(A) any portion of such facility that is used for inpatient hospital treatment of individuals dependent on, or addicted to, drugs or alcohol; and

(B) any private residence.

(3) Application of provisions

The provisions of paragraph (2) shall also apply to the provision of such routine or regular kindergarten, elementary or secondary education or library services in the facilities described in paragraph (2) not subject to paragraph (1).

(d) Notice

The prohibitions in subsections (a) through (c) of this section shall be incorporated by publication of a notice in the Federal Register by the Secretary (in consultation with the heads of other affected agencies) and by such agency heads in funding arrangements involving the provision of children's services administered by such heads. Such prohibitions shall be effective 90 days after such

notice is published, or 270 days after March 31, 1994, whichever occurs first.

(e) Special waiver

(1) In general

On receipt of an application, the head of the Federal agency may grant a special waiver to a person described in subsection (a) of this section who employs individuals who are members of a labor organization and provide children's services pursuant to a collective bargaining agreement that—

(A) took effect before March 31, 1994; and

(B) includes provisions relating to smoking privileges that are in violation of the requirements of this section.

(2) Termination of waiver

A special waiver granted under this subsection shall terminate on the earlier of—

(A) the first expiration date (after March 31, 1994) of the collective bargaining agreement containing the provisions relating to smoking privileges; or

(B) the date that is 1 year after March 31, 1994.

(f) Civil penalties

(1) In general

Any failure to comply with a prohibition in this section shall be a violation of this section and any person subject to such prohibition who commits such violation may be liable to the United States for a civil

penalty in an amount not to exceed $1,000 for each violation, or may be subject to an administrative compliance order, or both, as determined by the Secretary. Each day a violation continues shall constitute a separate violation. In the case of any civil penalty under this section, the total amount shall not exceed the amount of Federal funds received by such person for the fiscal year in which the continuing violations occurred. For the purpose of the prohibition in subsection (c) of this section, the term "person" shall mean the head of the applicable Federal agency or the contractor of such agency providing the services to children.

(2) Administrative proceeding

A civil penalty may be assessed in a written notice, or an administrative compliance order may be issued, by the Secretary only after an opportunity for a hearing in accordance with section 554 of title 5. Before making such assessment or issuing such order, or both, the Secretary shall give written notice thereof to such person by certified mail with return receipt and provide therein an opportunity to request in writing not later than 30 days after the date of receipt of such notice such hearing. The notice shall reasonably describe the violation and be accompanied with the procedures for such hearing and a simple form to request such hearing if such person desires to use such form. If a hearing is requested, the Secretary shall establish by such certified notice the time and place for such hearing which should be located, to the greatest extent possible, at a location convenient to such person. The Secretary (or the Secretary's designee) and such person may consult to

arrange a suitable date and location where appropriate.

(3) Circumstances affecting penalty or order

In determining the amount of the civil penalty or the nature of the administrative compliance order, the Secretary shall take into account, as appropriate—

(A) the nature, circumstances, extent, and gravity of the violation;

(B) with respect to the violator, any good faith efforts to comply, the importance of achieving early and permanent compliance, the ability to pay or comply, the effect of the penalty or order on the ability to continue operation, any prior history of the same kind of violation, the degree of culpability, and any demonstration of willingness to comply with the prohibitions of this section in a timely manner; and

(C) such other matters as justice may require.

(4) Modification

The Secretary may, as appropriate, compromise, modify, or remit, with or without conditions, any civil penalty or administrative compliance order. In the case of a civil penalty, the amount, as finally deterbined by the Secretary or agreed upon in compromise, may be deducted from any sums that the United States or its agencies or instrumentalities owes to the person against whom the penalty is assessed.

(5) Petition for review

Any person aggrieved by a penalty assessed or an order issued, or both, by the Secretary under this section may file a petition for judicial review thereof with

the United States Court of Appeals for the District ot Columbia Circuit or for any other circuit in which the person resides or transacts business. Such person shall provide a copy thereof to the Secretary or the Secretary's designee. The petition shall be filed within 30 days after the Secretary's assessment or order, or both, are final and have been provided to such person by certified mail. The Secretary shall promptly provide to the court a certified copy of the transcript of any hearing held under this section and a copy of the notice or order.

(6) Failure to comply

If a person fails to pay an assessment of a civil penalty or comply with an order, after either or both are final under this section, or after a court under paragraph (5) has entered a final judgment in favor of the Secretary, the Attorney General, at the request of the Secretary, shall recover the amount of the civil penalty (plus interest at then currently prevailing rates from the day either or both are final) or enforce the order in an action brought in the appropriate district court of the United States. In such action, the validity and appropriateness of the penalty or order or the amount of the penalty shall not be subject to review.

TITLE 21—FOOD AND DRUGS
CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER V—DRUGS AND DEVICES

Sec. 321. Definitions; generally

For the purposes of this chapter—

* * * *

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1)The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formularly, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph. A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

* * * *

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of diseaes or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

* * * *

(ff) The term "dietary supplement"—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title;

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does—

(A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include—

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of

this title, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

Except for purposes of subsection (g) of this section, a dietary supplement shall be deemed to be a food within the meaning of this chapter.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

Sec. 331. Prohibited acts

The following acts and the causing thereof are prohibited:

* * * *

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

* * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done

while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

* * * *

SUBCHAPTER V—DRUGS AND DEVICES

Sec. 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

* * * *

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

* * * *

(j) Health-endangering when used as prescribed

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

* * * *

Sec. 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date

but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of

the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to—

(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(ii) the holder of the approved applicant under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice

required by subparagraph (B) shall be given when the amended application is submitted.

(4)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act [42 U.S.C. 262], which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act [42 U.S.C. 262] (including all scientific and medical matters, chemistry, manufacturing, and controls).

* * * *

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giv-

ing him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of

adeqaute and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.

* * * *

Sec. 360e. Premarket approval

(a) General requirement

A class III device—

(1) which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval.

* * * *

(c) Application for premarket approval

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

* * * *

Sec. 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

* * * *

SUBCHAPTER IX—MISCELLANEOUS

Sec. 393. Food and Drug Administration

* * * *

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

(D) cosmetics are safe and properly labeled; and

(E) public health and safety are protected from electronic product radiation[ ]

* * * *

TITLE 42—THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A—PUBLIC HEALTH SERVICE
SUBCHAPTER III—A—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION
PART A—ORGANIZATION AND GENERAL AUTHORITY

Sec. 290aa-2. Reports: health consequences, current research, recommendations

(a) Alcoholism and alcohol abuse

The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) containing current information on health consequences of using alcoholic beverages,

(2) containing a description of current research findings made with respect to alcohol abuse and alcoholism, and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriiate.

(b) Drug abuse

The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) describing the health consequences and extent of drug abuse in the United States;

(2) describing current research findings made with respect to drug abuse, including current findings on the health effects of marihuana and the addictive property of tobacco; and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

* * * *

Sec. 290aa-4. Data collection

(a) Requirement of annual collection of data on mental illness and substance abuse

The Secretary, acting through the Administrator, shall collect data each year on—

(1) the national incidence and prevalence of the various forms of mental illness and substance abuse; and

(2) the incidence and prevalence of such various forms in major metropolitan areas selected by the Administrator.

(b) Requisite areas of data collection on mental health

With respect to the activities of the Administrator under subsection (a) of this section, relating to mental health, the Administrator shall ensure that such activities include, at a minimum, the collection of data on—

(1) the number and variety of public and nonprofit private treatment programs;

(2) the number and demographic characteristics of individuals receiving treatment through such programs;

(3) the type of care received by such individuals; and

(4) such other data as may be appropriate.

* * * *

SUBCHAPTER XVII—BLOCK GRANTS
PART B—BLOCK GRANTS REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE
SUBPART II—BLOCK GRANTS FOR PREVENTION AND TREATMENT OF SUBSTANCE ABUSE

Sec. 300x-26. State law regarding sale of tobacco products to individuals under age of 18

(a) Relevant law

(1) In general

Subject to paragraph (2), for fiscal year 1994 and subsequent fiscal years, the Secretary may make a grant under section 300x-21 of this title only if the State involved has in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18.

(2) Delayed applicability for certain States

In the case of a State whose legislature does not convene a regular session in fiscal year 1993, and in the case of a State whose legislature does not convene a regular session in fiscal year 1994, the requirement described in paragraph 1) as a condition of a receipt of a grant under section 300x-21 of this title shall apply only for fiscal year 1995 and subsequent fiscal years.

(b) Enforcement

(1) In general

For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant

under section 300x-21 of this title is that the State involved will enforce the law described in subsection (a) of this section in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18.

(2) Activities and reports regarding enforcement

For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section 300x-21 of this title is that the State involved will—

(A) annually conduct random, unannounced inspections to ensure compliance with the law described in subsection (a) of this section; and

(B) annually submit to the Secretary a report describing—

(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18; and

(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

(c) Noncompliance of State

Before making a grant under section 300x-21 of this title to a State for the first applicable fiscal year or any

subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (a) and (b) of this section. If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under such section for the State for the fiscal year involved by an amount equal to—

(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x-33 of this title for the State for the fiscal year;

(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x-33 of this title for the State for the fiscal year;

(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 300x-33 of this title for the State for the fiscal year; and

(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x-33 of this title for the State for the fiscal year.

* * * *

TITLE 49—TRANSPORTATION
CHAPTER 417—OPERATIONS OF CARRIERS

Sec. 41706. Prohibitions against smoking on scheduled flights

(a) General.—An individual may not smoke in the passenger cabin or lavatory of an aircraft on a scheduled airline flight segment in air transportation or intrastate air transportation that is—

(1) between places in a State of the United States, the District of Columbia, Puerto Rico, or the Virgin Islands;

(2) between a place in any jurisdiction referred to in clause (1) of this subsection (except Alaska and Hawaii) and a place in any other of those jurisdictions; or

(3)(A) scheduled for not more than 6 hours' duration; and

(B)(i) between a place referred to in clause (1) of this subsection (except Alaska and Hawaii) and Alaska or Hawaii; or

(ii) between Alaska and Hawaii.

(b) Regulations.—The Secretary of Transportation shall prescribe regulations necessary to carry out this section.